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# **Australia**

# **Agricultural Biotechnology Annual**

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### **Report Highlights:**

The federal government is very supportive of the technology, has committed considerable long-term funding to research and development. To date, biotech cotton, canola and carnation varieties are the only agricultural crops approved for commercial release into the environment in Australia. Australia requires that food products derived from GMOs, if they contain more than one percent of biotech product, get prior approval from Food Standards Australia New Zealand before they can be sold. Such products must also be labeled to indicate that they contain biotech products.

#### **SECTION I: EXECUTIVE SUMMARY**

The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof because of the impact this has on the ability of the U.S. to export to Australia. Unprocessed (whole) biotech corn and soybeans have not received regulatory approval in Australia and, thus, cannot be imported without further processing. Foods with biotech content of over 1 percent must receive prior approval and be labeled. This requirement can restrict sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other countries in the region, and elsewhere, which may follow Australia's lead in developing a regulatory system of their own.

The biotech debate is very important in Australia. The federal government is very supportive of the technology, has committed considerable long-term funding to research and development, and has approved genetically modified (GM) cotton, carnations and canola varieties for general release. The State governments have also committed funds for research and development, but most were more cautious about the introduction of the technology and most Australian states initially put in place moratoria on new plantings of biotechnology crops. After state-level reviews in November 2007, New South Wales and Victoria lifted the moratoria on genetically engineered canola. In November 2008, Western Australia lifted its ban to allow biotech cotton to be grown in the Ord River region and in April 2009 announced that trials of GM canola would be allowed. In early 2010, WA passed legislation allowing the commercial production of GM canola in that state. South Australia, Tasmania and the Australian Capital Territory (ACT) have maintained their moratoria. Major farm groups and the Commonwealth government's science organizations do not support this position and have argued openly for acceptance of biotech crops. Currently in Australia, about 95 percent of the cotton planted is from biotech varieties, which were approved for release prior to the state moratoria. Although GM cotton varieties dominate the cotton industry in Australia, the state moratoria slowed the commercialization and adoption of the technology for food crops.

Australia has a substantial risk assessment based regulatory framework for dealings with gene technology and genetically modified organisms, as well as a process for assessment and approval of genetically modified foods. The Gene Technology Act of 2000 established Australia's regulatory scheme for dealings with gene technology and genetically modified organisms (GMOs). The Commonwealth's Gene Technology Regulator serves the key role in assessing, regulating and licensing GMOs and enforcing license conditions. Genetically modified foods must also be assessed, determined to be safe, and be approved before being sold for human consumption. The standards for such foods are developed by Food Standards Australia New Zealand (FSANZ) and are contained in the Food Standards Code. There are labeling requirements for genetically modified foods containing modified genetic material and/or novel protein, and for foods with altered characteristics. Imports of viable GMOs and food products containing genetically modified ingredients need to meet these same regulations.

To date, biotech cotton, canola and carnation varieties are the only agricultural crops approved for commercial release into the environment in Australia. With the lifting of the moratoria in New South Wales, Victoria and Western Australia, plantings of GM canola are expected to continue to increase rapidly. Research is being conducted on other biotech crops, with field trials controlled by the OGTR being conducted on some, e.g. Indian mustard, wheat, sugarcane, white clover, grapevines, pineapple, papaya, canola and cotton (see Appendix II). Approval has already been granted for food products derived from biotech corn, cotton, soybean, sugar beet, potatoes, alfalfa and rice (see Appendix III).

For GMOs that have not received regulatory approval in Australia, U.S. export opportunities are obviously restricted. For the United States, the commercial impact of this constraint is most pronounced for feed grains, e.g. whole corn, and soybeans as these products have not yet received regulatory approval. In addition to this market access restriction, Australia does not allow the importation of many grains and/or grain products for phytosanitary reasons, citing the need to limit exotic weed seeds.

Australia requires that food products derived from GMOs, if they contain more than one percent of biotech product, get prior approval from Food Standards Australia New Zealand before they can be sold. Such products must also be labeled to indicate that they contain biotech products.

#### SECTION II: PLANT BIOTECHNOLOGY TRADE AND PRODUCTION

#### **Commercial Crops**

Biotech cotton, canola and carnations are the only crops approved for commercial release by Australia's Gene Technology Regulator. It is estimated that biotech cotton varieties are grown on up to 95 percent of Australia's cotton area. The Regulator approved the commercial releases of two biotech canola varieties in 2003. With the lifting of the moratoria in New South Wales and Victoria in early 2008, that was the first year that GM canola was grown commercially anywhere in the country. In November 2008, Western Australia lifted its ban to allow biotech cotton to be grown in the Ord River region and in April 2009 announced that trials of GM canola would be allowed at 20 sites in that state.

Biotech carnations became the first biotech products to be assessed by the Gene Technology Regulator to "pose minimal risks to people or the environment, and are sufficiently safe to be used by anyone without the need for a license" and they have accordingly been placed on the GMO Register.

### Biotech Cotton

Biotech cotton has been grown commercially in Australia since the approval and introduction of the first GM variety in 1996. Currently, around 95 percent of the Australian cotton crop is made up of GM varieties. In addition, there are a number of new biotech cotton varieties currently being developed (see Appendix II at the end of this report).

Australian food standards require approval and labeling of food or food ingredients that contain new genetic material or protein or have altered characteristics as a result of gene modification. Refined oil from biotech cottonseed, however, does not require a label because the oil contains no genetic material and the cottonseed oil is identical to conventional cottonseed oil.

#### Canola

Since 2003 a number of biotech canola varieties have been approved by OGTR. The first commercial plantings of these varieties took place in 2008 after the state governments in NSW and Victoria lifted their moratoria on commercial plantings of GM canola and in 2009 Western Australia also allowed trials to begin.

In 2011, an estimated 9% of the Australian canola crop was planted to biotech varieties (approx 164,000 ha). Trade sources report that the uptake of biotech canola varieties has slowed of late because the price spread between GM and conventional canola in European markets have been out as wide as \$50/MT. It is expected that approximately 175,000 hectares of GM canola will be grown in 2012 – 10% of the total canola crop. Industry sources indicate that GM canola seems to have found a niche in Western Australia, where plantings are likely to increase by more than the national average.

### **Applications under Evaluation**

A list of GMO applications currently under evaluation by OGTR is contained in Appendix I of this report.

### **Imported Products**

Under the Gene Technology Act 2000, approval or authorization must be obtained to deal with genetically modified organisms. This means that the importation of live, viable GMOs, are regulated under the Act. Importers need to apply to OGTR for a license or authorization to import any GMO into Australia. OGTR and the Australian Quarantine and Inspection Service (AQIS) work closely to regulate and enforce this situation. The AQIS application form for an import permit contains a section relating to the genetically modified status of the product.

Foods containing biotech materials must be approved by Food Standards Australia New Zealand and be labeled if the biotech content is greater than 1% before they can be sold in Australia. This applies to all domestically produced and imported food. A list of currently approved biotech food products is contained in Appendix III of this report.

Processed animal feeds, such as soy meal, are not covered by biotech legislation in Australia. These products, therefore, do not require prior approval or a license (see Section III of this report) to be imported. There are, however, quarantine restrictions on some products. Unprocessed biotech products imported as feed (i.e. whole grain, etc), would require a license from OGTR, as there is a possibility that seed could be released into the environment.

### **Products Developed Outside U.S.**

GM crops grown in Australia have been developed in Australia (see Appendices I & II for list of crops & their developers). Given that most of Australia's cotton products come from GM varieties, it is likely that any exports of cotton & cotton products would contain these varieties. Australia does not export cotton to the U.S. but in 2009, Australia exported 22.5 MT of cotton seed to the U.S. (tariff code 1207.20). There is no way of knowing for certain whether this seed was from GM or non-GM varieties.

### **SECTION III: PLANT BIOTECHNOLOGY POLICY**

### The GMO Regulatory System

The Gene Technology Act 2000 (the Act) came into force on June 21, 2001 as the Commonwealth component of a national regulatory scheme. The Act and the associated Gene Technology Regulations 2001, provide a comprehensive process for the Gene Technology Regulator to assess proposed dealings with live and viable GMOs ranging from contained work in certified laboratories to general releases of GMOs into the environment, and extensive powers to monitor and enforce license conditions. An Inter-Governmental Agreement, between the Commonwealth and the states and territories, underpins the system for regulating genetically modified organisms in Australia. The Ministerial Council for Gene Technology, comprising ministers from the Commonwealth and each state and territory, oversees the regulatory framework and provides advice to the Gene Technology Regulator on policy principles to assist in decision-making. The individual states and territories have passed or are developing complimentary legislation to the Gene Technology Act in their jurisdictions.

The object of the Gene Technology Act is: "To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms."

The Act prohibits all dealings with GMOs unless the dealing is:

- A licensed dealing;
- A notifiable low risk dealing;
- Exempt dealing; or
- Included on the GMO Register.

Key features of the Act are the appointment of an independent Gene Technology Regulator and a requirement for transparent and accountable implementation. The Regulator administers the regulation of all dealings with GMOs in Australia, in accordance with the Act and ensures compliance with the conditions of any approvals. The Regulator consults extensively with the community, research institutions and private enterprise.

The Gene Technology Regulator liaises with other regulatory agencies to coordinate the approval of biotech products for use and sale (see table below). The Act creates a Public Record of GMO Dealings and GM Products that resides on the OGTR website: www.ogtr.gov.au.

# Regulatory Agencies in Australia with a Role in Regulation of Gene Technology

Agency	What They Regulate	Scope	Relevant Legislation
OGTR – Office of the Gene Technology Regulatory (supporting the Gene Technology Regulator)	Dealings with GMOs	The Gene Technology Regulator administers a national scheme for the regulation of GMOs in Australia in order to protect health & safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.	Gene Technology Act 2000
<b>TGA</b> – Therapeutic Goods Administration	Medicines, medical devices, blood & tissues	TGA administers legislation that provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GM & GM-derived therapeutic products, & ensures their quality, safety & efficacy.	Therapeutic Goods Act 1989
FSANZ – Food Standards Australia & New Zealand	Food	FSANZ is responsible for setting standards for the safety, content and labeling of food. FSANZ conducts mandatory pre-market safety assessments for food produced using gene technology.	Food Standards Australia New Zealand Act 1991
<b>APVMA</b> – Australian Pesticides & Veterinary Medicines Authority	Agricultural & Veterinary Chemicals	APVMA operates the national system that regulates all agricultural chemicals (including those produced or used on GM crops) and veterinary therapeutic products. Assessments consider human and environmental safety, product efficacy (including insecticide and herbicide resistance management), and trade issues relating to residues	Agricultural & Veterinary Chemicals (Code) Act 1994  Agricultural & Veterinary Chemicals Administration Act 1994
NICNAS – National Industrial Chemicals Notification & Assessment Scheme	Industrial Chemicals	NICNAS provides a national notification & assessment scheme to protect the health of the public, workers & the environment from the harmful effects of industrial chemicals.	Industrial Chemicals (Notification & Assessment) Act 1989
<b>AQIS</b> – Australian Quarantine & Inspection Service	Quarantine	AQIS regulates the importation into Australia of all animal, plant & biological products that may pose a quarantine pest &/or disease risk. Import permit applications must indicate the presence of GMOs or GM material and the relevant authorization under the Gene Technology Act 2000.	Quarantine Act 1908 Imported Food Control Act 1992

The Act also establishes three committees to advise the Regulator and the Ministerial Council:

- The Gene Technology Technical Advisory Committee (GTTAC) a group of highly qualified experts who provide scientific and technical advice on applications;
- The Gene Technology Ethics Committee (GTEC) a group of expert ethicists, which provides ethical advice, particularly in the areas of law, religious practices, animal welfare and population health; and
- The Gene Technology Community Consultative Committee (GTCCC) a group of people representing the broad interests within the Australian community, including consumers, researchers, and environmentalists. This group looks beyond the science of gene technology to matters of general concern to the community in relation to GMOs.

#### **GMOs vs GM Product**

The Gene Technology Act 2000 distinguishes between genetically modified organisms (GMOs) and genetically modified (GM) products. A genetically modified product - 'GM product' - means a thing (other than a GMO) derived or produced from a GMO (Section 10 of the GT Act).

The Office of the Gene Technology Regulator (OGTR) does not directly regulate the use of GM products in Australia. However, the use of GM products is regulated by other regulatory agencies in a number of situations as set out in the table above.

### **GMOs Already Licensed by OGTR**

A list of GMOs already licensed by OGTR is contained in Appendix II of this report.

#### Biotech Food

Food Standards Australia New Zealand (FSANZ) is the Australian Government agency responsible for approving GM food products for the Australian market. Mandatory labeling of genetically modified foods, where introduced DNA or protein is present in the final food, came into force in Australia on December 7, 2001. Regulations for labeling are contained in <u>Standard 1.5.2</u> of the <u>Food Standards Code</u>. A list of currently approved biotech food products is contained in Appendix III of this report.

Under the Standard, food or ingredients labeled genetically modified contain new genetic material or protein as a result of the genetic modification or have altered characteristics, e.g. changed nutritional values, compared to the conventional food. Some flavorings may also be derived from genetically modified organisms, but labeling is only required if they are in a concentration of more than 1 gram per kilogram (0.1%). Food additives and processing aids do not need to be labeled unless the introduced genetic material is present in the final food.

Under the labeling standard, for packaged foods the words 'genetically modified' must be used in conjunction with the name of the food, or in association with the specific ingredient within the ingredient list; and for unpackaged foods for retail sale (such as unpackaged fruit and vegetables, or unpackaged processed or semi-processed foods) the words 'genetically modified' must be displayed in association with the food, or in association with the particular ingredient within that food.

#### **Biotech Feed Products**

Animal feeds containing GMOs (e.g. whole grains or oilseeds) are regulated by the OGTR. The OGTR considers any biosafety risks associated with the product and, if necessary, will apply special conditions, or may prohibit the use of the product as animal feed. As an example, after a GMO has undergone field trials, the organization conducting the trials may wish to use the unviable byproduct (such as seed) as animal feed. Before the product is used in any way, the Gene Technology Regulator will consider any risks and, if necessary, will apply conditions or disallow the product to be used.

The Australian Quarantine & Inspection Service (AQIS) and the OGTR must approve genetically modified whole grain commodities (including oilseeds) imported into Australia for animal feed (such as whole soybeans and corn). The AQIS provides quarantine inspection and certification for the arrival of imports of the products to ensure the product is free of pest and disease and specific license conditions are enforced to ensure the product meets requirements. The OGTR also assesses the product, issues a license to the organization importing the product, and may apply further conditions above those stipulated by AQIS.

Large amounts of biotech feed products are used in Australia's intensive livestock sector. A large proportion of Australia's soybean meal is imported, including from the United States. All cottonseed meal used in Australia is considered to be biotech as over 90 percent of the cotton crop is planted to biotech varieties. Biotech and non-biotech cotton varieties are not typically segregated in Australia.

Genetically modified animal feed does not require special labeling in Australia.

#### **Coexistence between Biotech & Non-Biotech Crops**

Coexistence of biotech, conventional, and organic crops has occurred in Australia since biotech cotton varieties were commercially grown in 1996. As part of any license to grow a biotech crop, OGTR stipulates the conditions under which the crop can be grown to ensure no cross-contamination with conventional or organic crops in the vicinity.

In October 2005, national consensus was achieved in Australia regarding practical thresholds to deal with the issue of traces of GM canola in conventional canola consignments and variety trials. The Primary Industries Ministerial Council (PIMC), which is comprised of Ministers from the Australian Government and each state and territory, agreed upon adventitious presence (AP) thresholds for the presence of GM canola in conventional grain and seed.

The PIMC meeting agreed on two thresholds:

- An AP threshold of 0.9 per cent GM canola in canola grain. This is the threshold supported by the Australian Oilseeds Federation (AOF).
- A second threshold for AP of GM canola in seed was set at 0.5 per cent for 2006 and 2007, to be reduced to 0.1 per cent thereafter. The Australian Seed Federation (ASF) established an AP threshold of 0.5 per cent GM seed in non-GM planting seed in 2003 following two years of research and consultation with the canola seed industry.

A number of projects on GMO supply chain management have been undertaken as part of the Department of Agriculture, Fisheries & Forestry's Biotechnology Strategy for Agriculture, Food and Fibre (BSAFF). These publications are available at: <a href="http://www.daff.gov.au/agriculture-food/biotechnology">http://www.daff.gov.au/agriculture-food/biotechnology</a>.

### **Biosafety Protocol**

Australia has not signed or ratified the Biosafety Protocol and the Australian Government has no timetable for consideration of accession to the Protocol. This was due to concerns about how the Protocol will operate in practice (documentation requirements, and the liability and compliance arrangements are yet to be agreed), uncertainty about how parties will implement the Protocol and whether they will do so in a way which respects all of their international obligations, and uncertainty about any individual country's capacity to influence decision-making. The Australian government considers that the Protocol is not needed for Australia to manage biotech imports as Australia already has a robust regulatory framework through the Office of Gene Technology Regulator.

#### SECTION IV: PLANT BIOTECHNOLOGY MARKETING ISSUES

#### **Market Acceptance**

Australia has a substantial, risk assessment based regulatory framework for dealings with gene technology and genetically modified organisms and the Government is supportive of the technology for its agricultural producers and has been an ally of the United States with regard to the Cartagena Protocol on Biosafety (CPB). This comes despite anti-biotechnology activism in Australia that promoted stringent labeling requirements and encouraged moratoria on biotechnology plantings. Australia's biotechnology sector is small in global terms, but growing, with over 440 biotechnology companies (this includes all types of biotechnology, not just agricultural biotechnology).

Major Australian commodity groups originally voiced concerns about introducing biotech canola and advocated for a 'go-slow' approach largely because of the potential impact biotech canola, which OGTR approved for commercial release in 2003, could have on their domestic and export businesses. In 2003 and 2004, several state governments (Victoria, NSW, South Australia, Western Australia, Tasmania and the ACT), using their powers over commodity 'marketing', imposed moratoria on the commercial release of products of biotechnology (with the exception of the previously approved cotton and carnations). Most of the moratoria were reviewed in 2007, and the states of NSW and Victoria lifted their bans on commercial plantings of GM canola and the first commercial crops were grown in these two states in 2008. In November 2008, the Western Australian government lifted their moratoria to allow GM cotton to be grown in the Ord River area and in April 2009 they also announced that trials of GM canola would be allowed at 20 sites in that state. Moratoria remain in place in South Australia, Tasmania and the ACT.

#### Northern Territory Commonwealth Legislation only (no moratorium) Queensland Commonwealth Legisla Western Australia tion only (no moratorium) GM Crop Free Area (excluding GM cotton in the Ord & GM canola) **New South Wales** GM cotton grown since 1996 & GM canola since 2008. Legislated moratorium on commercial GM food crops until 2011 unless approved by the Minister for Agriculture **Australian Capital Territory** Legislated moratorium on com mercial GM food crops until 2006+ South Australia Legislated moratorium on commercial GM food crops until 2019 Victoria Tasmania Commonwealth Legis-Legislated moratorium on comlation only (no morato mercial GM food crops until 2014

Australia
State Government GM Positions

Source: Agrifood Awareness Australia

Currently in Australia about 95 percent of the cotton planted is from biotech varieties, and there has been little controversy concerning its cultivation. Indeed, environmental benefits and the significant decline in pesticide and herbicide use for this crop have been widely reported. Biotech cottonseed does appear in the domestic market through the oil and meal, and this has not met with any major opposition.

In 2009, the Department of Innovation, Industry, Science and Research commissioned research on community attitudes to biotechnology the results of which were published at the end of 2010. Previous surveys had been conducted every two years from 1999, to determine public attitudes towards biotechnology and biotechnology applications in Australia. This survey was conducted between December 2009 and June 2010. See our report "Public Attitudes towards Agricultural Biotechnology in Australia," March 2011.

### Key findings of the report were:

- The Australian public has continued to strongly support biotechnologies that provide health or environmental benefits, but their support for genetically modified (GM) foods has dropped a little since 2007.
- Biotechnologies of key interest to the public include genetic modification (GM), cloning, stem cell research and using organisms to clean up pollution.
- GM food continues to be one of the least well supported biotechnologies, although the public perceive the benefits (70%) still outweigh the risks (48%). This is a drop from 2007 in benefits (77%) and risks (54%), yet still much higher than the 2005 figure of perceived benefits (64%) but lower than the 2005 figure of perceived risk at 71%.
- In 2009-10, GM food is more highly supported than foods containing preservatives and foods grown with pesticides. While 67% per cent of the public say that GM foods are acceptable, half of those opposed would change that position if there was long-term evidence of no harm being caused. About 45% per cent of those opposed to GM foods would change their position if labeling explained what ingredients had been modified and why. This support varies depending on the amount of GM in the food, why the modification was made and whether the food was a fruit and vegetable or other crop.

Other key findings include an increasing public trust in Australian regulators and a drop in perceived value of using biotechnologies to address climate change and to produce biofuels. Overall, support for health and medical applications of biotechnology was higher than support for applications in food or agriculture.

Full details of this report and those from previous years (2005 & 2007) & other information are available on the Department of Innovation, Industry, Science and Research website at: <a href="http://www.innovation.gov.au/Industry/Nanotechnology/PublicAwarenessandEngagement/Pages/ResearchandReports.aspx">http://www.innovation.gov.au/Industry/Nanotechnology/PublicAwarenessandEngagement/Pages/ResearchandReports.aspx</a>

A number of reports on market acceptance are also available on the DAFF website at: <a href="http://www.daff.gov.au/agriculture-food/biotechnology/reports">http://www.daff.gov.au/agriculture-food/biotechnology/reports</a>.

#### **Country Specific Studies Relevant to U.S. Exporters**

The **Department of Agriculture, Fisheries & Forestry** has a number of publications, studies and fact sheets available on the <u>Agriculture & Food Biotechnology page</u>.

<u>Agrifood Awareness Australia</u> – This organization publishes a large number of bulletins and information guides.

The <u>Australian Bureau of Agriculture & Resource Economics (ABARE)</u> has released a large number of studies & papers on GM industries. Conduct a search for GM on the ABARE website.

In September 2007, the **National Farmers Federation** released a <u>Gene Technology Policy</u> recognizing the potential of biotechnology as a valuable tool within agricultural production systems and urging that all potential benefits should be available to farmers to make informed choice in their farming decisions.

### **SECTION V: ANIMAL BIOTECHNOLOGY**

There is a small amount of work currently being conducted in Australia on genetically engineered agriculturally-relevant animals – mainly chicken & sheep. The work is in the very early stages and is being carried out by public and private research institutions and universities. GE animals are considered 'Notifiable Low Risk Dealings' (NLRDs) by the OGTR – i.e. "dealings with GMOs that have been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met." A full list of NLRDs, including the institutions carrying out the research, is available on the OGTR website at: <a href="http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrdclass-2">http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrdclass-2</a>.

No GE animals are currently anywhere near the commercial production stage in Australia.

### **SECTION VI: REFERENCE MATERIAL**

Below are links to various organizations involved in the agricultural biotechnology sector in Australia.

### Australian Government

Office of the Gene Technology Regulator

Food Standards Australia New Zealand

<u>Australian Pesticides & Veterinary Medicines Authority</u>

Department of Agriculture, Fisheries & Forestry

Department of Innovation, Industry, Science & Research

Commonwealth Scientific & Industrial Research Organization (CSIRO)

### Other Organizations

Agrifood Awareness Australia

**National Farmers Federation** 

### **APPENDIX I: GMO APPLICATIONS UNDER EVALUATION**

The Office of the Gene Technology Register has received the following applications for evaluation. All applications are posted on the OGTR website when they are first received and again when public comment is sought. Full details of all applications can be found at: <a href="http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-evaluation-1">http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-evaluation-1</a>

Product	Trait Category	Applicant	Status
Cotton	Limited and controlled release of cotton genetically modified for enhanced fiber yield	The Commonwealth Scientific and Industrial Research Organisation (CSIRO)	Notification posted 22 Feb 2012 Public calls for comment open 21 May 2012

### APPENDIX II: GMOS ALREADY LICENSED FOR USE IN AUSTRALIA

The table below provides summary information about all current Dealings for Intentional Release (DIRs) on the GMO Record (i.e. granted licenses for various uses). Full details of all applications (including those withdrawn and surrendered and those released for commercial use) can be found on the OGTR website at: <a href="http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1">http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1</a>

Crop	Applicant	Modified Trait	License Purpose
Canola (Brassica napus L.)	Pioneer Hi- Bred Australia Pty Ltd	Herbicide tolerance	Limited and controlled release of canola genetically modified for herbicide tolerance
Cotton (Gossypium hirsutum L.)	Bayer CropScience Pty Ltd	Insect resistance, Herbicide tolerance, Selectable marker - antibiotic	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Wheat & barley (Triticum aestivum L. &Hordeum vulgare L.)	CSIRO	Composition - food (human nutrition), Yield, Selectable marker - antibiotic	Limited and controlled release of wheat and barley genetically modified for altered grain composition and nutrient utilization efficiency
Wheat & barley (Triticum aestivum L. & Hordeum vulgare L.)	CSIRO	Composition - food (human nutrition), Yield, Disease resistance, Abiotic stress tolerance, Selectable marker - antibiotic, Selectable marker - herbicide	Limited and controlled release of wheat and barley genetically modified for altered grain composition, nutrient utilization efficiency, disease resistance or stress tolerance
Banana (Musa spp.)	Queensland University of Technology	Composition - food (human nutrition), Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of banana genetically modified for enhanced nutrition
Canola (Brassica napus L.)	Bayer CropScience Pty Ltd	Herbicide tolerance/Hybrid breeding system	Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (GM InVigor® x Roundup Ready® canola)
Banana ( <i>Musa</i> spp.)	Queensland University of Technology	Disease resistance, Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of banana genetically modified for disease resistance
Canola ( <i>Brassica napus</i> L.)	Monsanto Australia Ltd	Herbicide tolerance	Limited and controlled release of canola genetically modified for herbicide tolerance

Canola (Brassica napus L.) & Indian mustard (Brassica juncea L.) Czern	Bayer CropScience Pty Ltd	Herbicide tolerance, Plant development, Selectable marker - herbicide	Limited and controlled release of canola and Indian mustard genetically modified for herbicide tolerance and/or a hybrid breeding system
Canola ( <i>Brassica napus</i> L.)	Victorian Department of Primary Industries	Yield, Plant development, Selectable marker - antibiotic	Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence
Wheat & Barley (Triticum aestivum L. & Hordeum vulgare L.)	The University of Adelaide	Abiotic stress tolerance, Yield, Composition - food (human nutrition), Selectable marker - antiobiotic	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance
Cotton (Gossypium hirsutum L.)	Monsanto Australia Ltd	Insect resistance, Herbicide tolerance, Selectable marker - herbicide, Selectable marker - antiobiotic, Reporter gene expression	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Wheat ( <i>Triticum</i> aestivum L.)	CSIRO	Yield, Abiotic stress tolerance, Selectable marker - herbicide, Selectable marker - antibiotic	Limited and controlled release of wheat genetically modified for enhanced carbon assimilation in drought and heat prone environments
Wheat & Barley (Triticum aestivum L. & Hordeum vulgare L.)	CSIRO	Composition - food (human nutrition), Yield, Selectable marker - antibiotic	Limited and controlled release of wheat and barley genetically modified for altered grain composition or nutrient utilization efficiency
Bovine parainfluenza virus (Medi 534) (Bovine parainfluenza virus type 3)	PPD Australia Pty Ltd	Vaccine - attenuation, Vaccine - antigen expression	Limited and controlled release of a genetically modified vaccine for prevention of selected childhood respiratory diseases
<b>Sugarcane</b> (Saccharum spp.)	BSES Limited	Herbicide tolerance, Selectable marker - herbicide, Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of sugarcane genetically modified for herbicide tolerance

Sugarcane (Saccharum spp.)	BSES Limited	Plant development, Abiotic stress tolerance, Yield, Composition - non-food (processing), Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of sugarcane genetically modified for altered plant growth, enhanced drought tolerance, enhanced nitrogen use efficiency, altered sucrose accumulation, and improved cellulosic ethanol production from sugarcane biomass
Wheat & Barley (Triticum aestivum L. & Hordeum vulgare L.)	CSIRO	Yield, Selectable marker - antibiotic	Limited and controlled release of wheat and barley genetically modified for enhanced nutrient utilization efficiency
Wheat & Barley (Triticum aestivum L. & Hordeum vulgare L.)	CSIRO	Composition - food (human nutrition), Selectable marker - antibiotic	Limited and controlled release of wheat and barley genetically modified for altered grain starch composition
Wheat (Triticum aestivum L.)	CSIRO	Composition - food (human nutrition), Composition - food (processing), Selectable marker -antibiotic	Limited and controlled release of wheat genetically modified for altered grain composition
Cotton (Gossypium hirsutum L.)	Dow AgroSciences Australia Pty Ltd	Insect resistance, Herbicide tolerance, Selectable marker - herbicide	Commercial release of cotton genetically modified for insect resistance (WideStrike <sup>™</sup> Insect Protection Cotton)
Rose (Rosa X hybrida)	Florigene Pty Ltd	Aesthetic quality, Selectable marker - antibiotic	Commercial release of rose genetically modified for altered flower color
White Clover (Trifolium repens L.)	Victorian Department of Primary Industries	Disease resistance, Selectable marker - antibiotic	Limited and controlled release of white clover genetically modified to resist infection by Alfalfa mosaic virus
Maize (corn) (Zea mays L.)	CSIRO	Gene tagging, Selectable marker -antibiotic, Selectable marker - herbicide, Reporter gene expression	Limited and controlled release of maize genetically modified to investigate gene function
Cotton (Gossypium hirsutum L.)	CSIRO	Composition - food (processing), Selectable marker - antibiotic	Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil

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Perennial ryegrass & tall fescue (Lolium perenne L.) & (Lolium arundinaceum) (Schreb.) Darbysh	Victorian Department of Primary Industries	Composition - animal nutrition, Selectable marker - antibiotic	Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities
Bread Wheat (Triticum aestivum L.)	Victorian Department of Primary Industries	Abiotic stress tolerance, Selectable marker - herbicide	Limited and controlled release of wheat genetically modified for drought tolerance
<b>Banana</b> ( <i>Musa. acuminata</i> cv. Grande Naine)	Queensland University of Technology	Disease resistance, Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of banana genetically modified for disease resistance
Sugarcane (Saccharum spp.)	The University of Queensland	Product quality - food, Selectable marker - antibiotic	Limited and controlled release of sugarcane genetically modified for altered sugar production
Wheat & barley (Triticum aestivum) & (Hordeum vulgare)	The University of Adelaide	Abiotic stress tolerance, Composition - food (human nutrition), Selectable marker - antibiotic	Limited and controlled release of wheat and barley genetically modified for enhanced tolerance to abiotic stresses or increased beta glucan
Banana ( <i>Musa. acuminata</i> cv. Williams)	Queensland University of Technology	Composition - food (human nutrition), Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of banana genetically modified for enhanced nutrition
Cotton (Gossypium barbadense L.)	Monsanto Australia Ltd	Insect resistance, Herbicide tolerance, Selectable marker - herbicide, Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of GM insect resistant and/or herbicide tolerant Gossypium barbadense cotton
Bread wheat (Triticum aestivum L.)	Victorian Department of Primary Industries	Abiotic stress tolerance, Selectable marker - herbicide	Limited and Controlled Release of GM drought tolerant wheat
Sugarcane (Saccharum spp.)	BSES Limited	Plant development, Abiotic stress tolerance, Yield, Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of GM sugarcane with altered plant architecture, enhanced water or improved nitrogen use efficiency
Canola & Indian Mustard (Brassica napus L. & Brassica juncea L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, Hybrid breeding system, Selectable marker - herbicide	Limited and controlled release of GM herbicide tolerant hybrid <i>Brassica napus</i> and hybrid <i>Brassica juncea</i>

		Herbicide tolerance, Insect resistance,	
Cotton		Selectable marker -	Commercial release of GM
(Gossypium	Monsanto	herbicide, Selectable	herbicide tolerant and/or
hirsutum L.)	Australia Ltd	marker - antibiotic,	insect resistant cotton lines
,		Reporter gene	north of latitude 22° South
		expression	
Cotton		Disease resistance,	Field trial of GM cotton
(Gossypium	Hexima Ltd	Selectable marker -	expressing natural plant
hirsutum L.)		antibiotic	genes for fungal control
Cotton	Bayer	Herbicide tolerance,	Commercial release of
(Gossypium	CropScience	Selectable marker -	herbicide tolerant Liberty
hirsutum L.)	Pty Ltd	herbicide	Link <sup>®</sup> Cotton
Indian mustard			
(includes Brown	Bayer	Herbicide tolerance,	Field trials of genetically
& Oriental	CropScience	Plant development,	modified herbicide tolerant,
mustard)	Pty Ltd	Selectable marker -	hybrid Brassica juncea
(Brassica juncea	,	herbicide	nysma shassica jameea
L. Czern &Coss.)			F: 11. : 1. 6
Sugarcane		Product quality - food,	Field trial of genetically
(Saccharum	The University	Selectable marker -	modified (GM) sugarcane
officinarum L. x S.	of Queensland	antibiotic	expressing sucrose
spontaneum L.)	Victorian		isomerase Field Evaluation of
White Clover		Disease resistance,	
(Trifolium repens	Department of Primary	Selectable marker -	Genetically Modified White Clover Resistant to Infection
L.)	Industries	antibiotic	by Alfalfa Mosaic Virus
Fowl adenovirus	industries		
(Fowl adenovirus,	Imugene		Limited and controlled
serotype 8, isolate	Limited	Vaccine - attenuation	release of GM fowl
CFA44)			adenovirus (FAV)
,	Dow		Agronomic assessment and seed increase of transgenic
Cotton	AgroSciences	Insect resistance,	cottons expressing
(Gossypium	Australia Pty	Selectable marker -	insecticidal genes (cry1Ac
hirsutum L.)	Ltd	herbicide	and cry1Fa) from Bacillus
			thuringiensis
Canala	Dayon	Herbicide tolerance,	Field Trial - Seed increase
Canola	Bayer	Plant development,	and field evaluation of
(Brassica napus	CropScience	Selectable marker -	herbicide tolerant hybrid
L.)	Pty Ltd	herbicide	canola
	Queensland	Product quality - food,	Field trial of pineapple plants
Pineapple	Department of	Plant development,	modified for blackheart
(Ananas comosus)	Primary	Selectable marker -	reduction and to delay
(, manas comosas)	Industries	antibiotic, Reporter gene	flowering
		expression	
		Product quality - food,	Field trial for evaluation of
Papaya	The University	Selectable marker -	GM papaya to delay fruit
(Carica papaya)	of Queensland	antibiotic, Reporter gene	ripening and to test the
		expression	expression of the introduced
	1		genes

Canola (Brassica napus L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, Plant development, Selectable marker - herbicide	Commercial release of InVigor® hybrid canola (Brassica napus) for use in the Australian cropping system
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### **APPENDIX III: APPROVED GM FOOD PRODUCTS**

The following table contains a current list of approved biotech food products. Detailed information is contained in  $\underline{\text{Standard 1.5.2}}$  on the FSANZ web site.

Commodity	Food produced using gene technology	Special conditions
Canola	Food derived from herbicide- tolerant canola line GT73 Food derived from herbicide- tolerant canola Topas 19/2 and T45 and herbicide- tolerant and pollination- controlled lines Ms1, Ms8, Rf1, Rf2, Rf3 Food derived from herbicide- tolerant canola line Westar- Oxy-235	
Corn	Food derived from herbicide- tolerant corn line GA21 Food derived from insect- protected corn line MON810 Food derived from herbicide- tolerant and insect- protected corn line Bt11 Food derived from insect- protected corn line Bt176 Food derived from herbicide- tolerant corn line T25 Food derived from herbicide- tolerant corn line NK603 Food derived from herbicide tolerant and insect- protected corn line DBT418 Food derived from herbicide- tolerant and insect- protected corn line 1507 Food derived from insect- protected corn line MON863 Food derived from herbicide- tolerant and insect- protected corn line DAS- 59122-7 Food derived from herbicide- tolerant and insect- protected corn line MON86017 Food derived from insect- protected corn line MIR604	

	Food derived from high lysine corn line LY038  Food derived from amylase modified corn line 3272 Food derived from insect-protected corn line MON89034 Food derived from insect-protected corn line MIR162 Food derived from herbicide-tolerant corn line DP-098140-6 Food derived from drought-tolerant corn line MON87460 Food derived from herbicide-tolerant corn line DAS-40278-9	Unless the protein content has been removed as part of a refining process, the label on or attached to a package of a food derived from high lysine corn line LY038 must include a statement to the effect that the food has been genetically modified to contain increased levels of lysine.
	Food derived from insect- protected corn line 5307	
Cotton	Food derived from insect- protected cotton lines 531, 757 and 1076 Food derived from herbicide- tolerant cotton line 1445 Food derived from herbicide- tolerant cotton lines 10211 and 10222 Food derived from insect- protected cotton line 15985 Food derived from insect- protected cotton line COT102 Food derived from herbicide- tolerant and insect- protected cotton line MXB- 13 Food derived from herbicide- tolerant cotton line LL25 Food derived from herbicide- tolerant cotton line MON88913 Food derived from herbicide- tolerant cotton line GHB614	

	Food derived from insect- protected cotton line COT67B Food derived from herbicide- tolerant and insect- protected cotton line T304- 40 Food derived from herbicide- tolerant and insect- protected cotton line GHB119	
Lucerne	Food derived from herbicide- tolerant lucerne lines J101 & J163	
Potato	Food derived from insect- protected potato lines BT- 06, ATBT04-06, ATBT04- 31, ATBT04-36, and SPBT02-05 Food derived from insect- and virus-protected potato lines RBMT21-129, RBMT21-350 and RBMT22-82 Food derived from insect- and virus-protected potato lines RBMT15-101, SEM15-02 and SEM15-15	
Rice	Food derived from herbicide- tolerant rice line LLRICE62	
Soybean	Food derived from herbicide- tolerant soybean line 40-3- 2 Food derived from herbicide- tolerant soybean lines A2704-12 and A5547-127 Food derived from herbicide- tolerant soybean line MON89788 Food derived from herbicide- tolerant soybean line DP- 356043-5 Food derived from high oleic acid soybean line DP- 305423-1 Food derived from insect- protected soybean line MON87701	

	Food derived from herbicide- tolerant high oleic acid soybean line MON87705  Food derived from soybean line MON87769 producing stearidonic acid	
	Food derived from herbicide- tolerant soybean line DAS- 68416-4 Food derived from herbicide- tolerant soybean line FG72	
Sugarbeet	Food derived from herbicide- tolerant sugarbeet line 77 Food derived from herbicide- tolerant sugarbeet line H7- 1	

## **Recent Reports from FAS/Canberra**

The reports listed below can all be downloaded from the FAS website at: <a href="http://www.fas.usda.gov/scriptsw/AttacheRep/default.asp">http://www.fas.usda.gov/scriptsw/AttacheRep/default.asp</a>.

Title of Report	Date
Biofuels Annual 2012	06/27/12
Retail Sector Report	06/11/12
Dairy and Products Semi Annual 2012	05/07/12
Sugar Annual 2012	04/10/12
Cotton and Products Annual 2012	03/29/12
Grain and Feed Annual 2012	03/20/12
Wine Annual 2012	03/15/12
Livestock and Product Semi-annual 2012	03/13/12
Grain & Feed Lock-Up - February 2012	01/24/12